



General

Guideline Title

ACR Appropriateness Criteria® colorectal cancer screening.

Bibliographic Source(s)

Yee J, Kim DH, Rosen MP, Lalani T, Carucci LR, Cash BD, Feig BW, Fowler KJ, Katz DS, Smith MP, Yaghmai V, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® colorectal cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 12 p. [90 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Yee J, Rosen MP, Blake MA, Baker ME, Cash BD, Fidler JL, Grant TH, Greene FL, Jones B, Katz DS, Lalani T, Miller FH, Small WC, Sudakoff GS, Warshauer DM, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® colorectal cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2010. 9 p.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Colorectal Cancer Screening

Variant 1: Average-risk individual: age ≥50 years.

Radiologic Procedure	Rating	Comments	RRL*
CT colonography every 5 years after negative screen	9		☼☼☼
X-ray barium enema double-contrast every 5 years after negative screen	6		☼☼☼
X-ray barium enema single-contrast every 5 years after negative screen	4	Use this procedure if CTC or DCBE cannot be performed.	☼☼☼
MR colonography every 5 years after negative screen	4		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative

Radiologic Procedure	Rating	Comments	Radiation RRL Level
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Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Average-risk individual after positive fecal occult blood test (FOBT), indicating a relative elevation in risk.

Radiologic Procedure	Rating	Comments	RRL*
CT colonography	9		☢☢☢
X-ray barium enema double-contrast	6		☢☢☢
X-ray barium enema single-contrast	4	Use this procedure if CTC or DCBE cannot be performed.	☢☢☢
MR colonography	4		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Average-, moderate-, or high-risk individual after incomplete colonoscopy.

Radiologic Procedure	Rating	Comments	RRL*
CT colonography	9		☢☢☢
X-ray barium enema double-contrast	6		☢☢☢
X-ray barium enema single-contrast	4	Use this procedure if CTC or DCBE cannot be performed.	☢☢☢
MR colonography	3		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Moderate-risk individual: personal history of adenoma or carcinoma or first-degree family history of cancer or adenoma.

Radiologic Procedure	Rating	Comments	RRL*
CT colonography every 5 years after negative screen	9		☢☢☢
X-ray barium enema double-contrast every 5 years after negative screen	6		☢☢☢
X-ray barium enema single-contrast every 5 years after negative screen	4	Use this procedure if CTC or DCBE cannot be performed.	☢☢☢
MR colonography every 5 years after negative screen	4		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 5: High-risk individual: hereditary nonpolyposis colorectal cancer.

Radiologic Procedure	Rating	Comments	RRL*
CT colonography	3	Colonoscopy is the preferred procedure.	☢☢☢
X-ray barium enema double-contrast	2	Colonoscopy is the preferred procedure.	☢☢☢
MR colonography	2		O
X-ray barium enema single-contrast	1	Use this procedure if CTC or DCBE cannot be performed.	☢☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 6: High-risk individual: ulcerative colitis or Crohn colitis.

Radiologic Procedure	Rating	Comments	RRL*
CT colonography	3	Colonoscopy is the preferred procedure for its ability to obtain biopsies to look for dysplasia.	☢☢☢
X-ray barium enema double-contrast	2	Colonoscopy is the preferred procedure for its ability to obtain biopsies to look for dysplasia.	☢☢☢
MR colonography	2	Colonoscopy is the preferred procedure for its ability to obtain biopsies to look for dysplasia.	O
X-ray barium enema single-contrast	1	Colonoscopy is the preferred procedure for its ability to obtain biopsies to look for dysplasia.	☢☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

Colorectal cancer is the third leading cause of cancer deaths in the United States. An average-risk individual has an approximately 5% lifetime risk of developing colorectal cancer. Detecting the disease when it is localized has long been associated with a 5-year survival rate of approximately 80%. Also, evidence has accumulated to support the concept that almost all colorectal cancers develop from benign adenomas and that, in most cases, this transformation process is slow, requiring an average of 10 years. More recently, a second pathway, mediated through benign hyperplastic or serrated polyps, has also been identified to have a long dwell time. However, such screening involves exposing healthy, asymptomatic individuals to tests that impose a financial burden on society and have the potential for physical and psychological injury to the patient. Thus, the decision to promote screening requires scientific evidence that it can be used to reduce mortality in a safe and cost-effective manner. Information extrapolated from symptomatic populations is not sufficient because of the possible influence of lead-time and length-time bias. In addition, determining whom to screen, how to screen, and how often to screen requires a complex integration of an individual's risk level, the test performance characteristics (sensitivity, specificity), the safety and cost of the screening options, and the natural history and prevalence of the target lesions.

Evidence from 3 randomized controlled trials using fecal occult blood testing (FOBT) in average-risk individuals (age ≥ 50 years) demonstrated a 15% to 33% mortality reduction. A nonrandomized trial with historical controls reported a reduction in the incidence of colon cancer by using colonoscopy to remove adenomas. Long-term follow-up after colonoscopic polypectomy has been found to result in a 53% reduction in mortality. A case-control study demonstrated that screening sigmoidoscopy decreased colorectal cancer mortality by two-thirds for cancers within reach of the sigmoidoscope, and another case-control study reported a reduction in the incidence of and mortality from colorectal cancer after removing adenomas in patients who had undergone colonic endoscopy because of symptoms. Results from these case-control studies have suggested a protective effect lasting 5 to 10 years after direct structural examination of the colon. The issue yet to be clarified is the potential benefit from the various screening options, the magnitude of which depends highly on test sensitivity, recommended test intervals, and the need to detect and

remove all colonic polyps.

The prevalence of adenomas in the general population is 30% to 50% and increases with age. Most adenomas are diminutive (≤ 5 mm) or small (6–9 mm) in size. The rate of carcinoma is very low in subcentimeter adenomas, reported at 0.03% in diminutive polyps and 0.2% for 6- to 9-mm polyps. Even in larger adenomas measuring 10 to 20 mm in size, the rate remains relatively low—below 2%. Over time, only a tiny minority of all adenomas ultimately progress to cancer. The vast majority remain stable or regress over time. A longitudinal colonoscopic study reported a tendency for net regression in 6- to 9-mm adenomas over a 3-year period. On the other hand, adenomas >25 mm have a 10% chance of containing invasive cancer; polyps ≥ 10 mm have an 8% chance of progressing to invasive cancer at 10 years, which increases to 24% at 20 years. Individuals with a history of such neoplasms appear to have an increased probability of developing colorectal cancer in the future, whereas those who have had fewer than 3 small adenomas have a subsequent cancer risk similar to that of the general population.

A joint guideline from the American Cancer Society (ACS), the U.S. Multi-Society Task Force on Colorectal Cancer (USMSTF), and the American College of Radiology (ACR) has divided colorectal cancer risk levels into 3 categories: 1) average (individuals ≥ 50 years of age), 2) moderate (individuals with a personal history of a large adenoma or carcinoma or a first-degree relative with a history of adenoma or carcinoma), and 3) high (individuals with hereditary syndromes, such as hereditary nonpolyposis colorectal cancer and familial polyposis, or a personal history of ulcerative colitis or Crohn colitis).

The magnitude of risk for an individual who has a single, first-degree relative with colorectal cancer is approximately 2 to 3 times that of the general population. The risk increases as the number of first-degree relatives with the disease increases. In addition, the cancer tends to develop at a younger age, depending on the age at which the relative developed a neoplasm. The degree of risk for individuals with a personal history of neoplasm is unclear, because all the information on this subject was derived from the precolonoscopy era when complete colonic clearing was not performed; theoretically, then, residual synchronous lesions could have evolved. There is no evidence to indicate that the natural history of the disease in the 2 moderate-risk groups differs from that in the average-risk group. The probability of an individual with a hereditary nonpolyposis syndrome developing colorectal cancer may be as high as 50%.

The natural history of the disease in moderate risk individuals is uncertain. A nonrandomized controlled trial of such a population screened at 3-year intervals with a double-contrast barium enema (DCBE) and sigmoidoscopy or colonoscopy reported a significant reduction in cancer incidence.

The risk of cancer in individuals with ulcerative colitis increases after the disease has been present 8 to 10 years, and it correlates with the extent of the disease. The best estimates of risk are 5% after 10 to 20 years of disease and 9% per year thereafter. The risk for individuals with Crohn colitis may be comparable. Unlike the other forms of colorectal cancer screening, the screening of ulcerative colitis patients focuses on detecting dysplasia (which may be flat and identified only by random biopsies, or it may be macroscopically visible) and a subsequent prophylactic colectomy. There is no evidence of a reduction in mortality resulting from colorectal cancer screening in these patients, although annual colonoscopy screening has demonstrated a shift to early-stage detection. For patients at high risk due to known ulcerative colitis or Crohn colitis, a colonoscopy is preferred over computed tomography colonography (CTC), magnetic resonance imaging (MRI), or barium examinations due to its ability to obtain biopsies to look for dysplasia.

Current Colorectal Cancer Screening Recommendations

A discussion of the nonradiologic tests for colorectal cancer screening is beyond the scope of this document. However, of the structural tests available, colonoscopy is currently considered to be the most sensitive and specific for detecting colorectal polyps and cancers. A number of organizations—including the World Health Organization, the United States Agency for Health Care Policy and Research, and the United States Preventive Service Task Force—have issued or endorsed guidelines for colorectal cancer screening, which are presented as lists of options. For average-risk individuals, the options include annual or biennial FOBT, flexible sigmoidoscopy every 5 years, and colonoscopy every 10 years. The current joint ACS, USMSTF, and ACR guideline for colorectal cancer screening includes a DCBE or CTC every 5 years on the list of options for average-risk individuals. These guidelines also separate colorectal cancer screening tools into two categories: 1) those that can screen for both adenomatous polyps and cancer (flexible sigmoidoscopy, DCBE, CTC, and colonoscopy); and 2) those that are intended to screen for cancer only (FOBT, fecal immunochemical test, and stool DNA test). There are more specific recommendations for individuals who are at an increased risk for colorectal neoplasia.

Double-contrast Barium Enema

A retrospective study evaluated the diagnostic yield of DCBE examinations performed for colorectal cancer screening in average-risk individuals >50 years of age. The diagnostic yield was 5.1% for neoplastic lesions ≥ 10 mm and 6.2% for advanced neoplastic lesions, regardless of size. These diagnostic yields fall within the lower range of those reported for screening colonoscopy (5.0%–9.5% for colonic neoplasms ≥ 10 mm and 4.6%–11.7% for advanced colonic neoplasms, regardless of size).

The best data on the effectiveness of the DCBE for detecting colorectal cancer come from studies in which the imaging history of patients with colorectal cancer was reviewed. Based on this methodology, the sensitivity of DCBE ranges from 75 to 95%. When considering only localized cancer, the sensitivity varies from 58% to 94%. In studies comparing the DCBE to endoscopy, the sensitivity has been 80% to 100%, and when used to evaluate individuals with a positive FOBT, most reports indicate a sensitivity of 75% to 80%. This correlates with a large, population-based study that found the overall rate of new or missed cancers following a DCBE was 22%. The sensitivity of DCBE for detecting large adenomas has been best studied when all subjects underwent both radiologic and endoscopic procedures. With this study design, sensitivity has ranged from 48% to 81%.

It has been determined that the specificity of a DCBE for detecting large adenomas is 96%, and the negative predictive value is 98%. It has been frequently suggested that the DCBE is less effective at demonstrating polyps in the rectosigmoid colon. However, well-designed studies have shown that sensitivity figures for the DCBE in this anatomic region are comparable to those in other colonic sites. The diagnostic yield of the DCBE can be increased by supplementing it with a flexible sigmoidoscopy. In the workup of a positive FOBT, the combination of the two procedures detected 98% of large polyps and cancers. A cost-effectiveness analysis demonstrated that a DCBE performed every 5 to 10 years costs less than \$22,000 per life-year saved for a possible range of natural history, which is far below the standard of \$40,000. A DCBE is a safe procedure, with a perforation rate of approximately 1 in 25,000. The perforation rates associated with other colorectal examinations are 1 in 22,000 for CTC, 1 in 10,000 for a flexible sigmoidoscopy, and 1 in 1,000 for a diagnostic colonoscopy.

Single-contrast Barium Enema

A preponderance of the literature has demonstrated a markedly inferior performance profile for the single-contrast barium enema (SCBE). A minority of studies have suggested that a SCBE has the potential to be as sensitive as the DCBE for detecting cancer and large polyps. The reported sensitivity for cancer ranges from 82% to 95% and is approximately 95% for large polyps. However, because of the paucity of studies and limitations of the study designs, questions have been raised about the reproducibility of the results, particularly for large polyps. In an FOBT trial, SCBE was used as a diagnostic follow-up. The sensitivity for cancer was 80%.

Computed Tomography Colonography

CTC (also known as "virtual colonoscopy") was introduced in 1994 as a less invasive method of imaging the colon by using helical CT. Early CTC trials performed with single-detector CT scanners demonstrated sensitivities of 59% to 92% and specificities of 82% to 98% for polyps ≥ 10 mm. A meta-analysis of these early trials confirmed reasonably high, pooled sensitivities of 88% and 81% by patient and lesion, respectively, with a pooled specificity of 95% for polyps ≥ 10 mm [52]. Studies performed with 4-detector-row scanners have demonstrated sensitivities and specificities of 82% to 100% and 90% to 98%, respectively, for polyps ≥ 10 mm. However, most of these trials were not performed on screening populations but on individuals who were at an increased risk for colorectal neoplasia. A trial performed on 307 asymptomatic subjects using a 64 multidetector-row CT demonstrated a CTC sensitivity and specificity of 91% and 93%, respectively, for polyps >6 mm and 92% and 98%, respectively, for polyps ≥ 10 mm.

Two other meta-analyses of CTC performance in detecting ≥ 10 mm polyps showed pooled sensitivities by patient of 85% and 93%, with pooled specificities of 97%. One meta-analysis compared 7 studies that used multidetector CT with 9 studies that used single-detector CT and found that multidetector CT had a high overall sensitivity of 95% for polyp detection, whereas single-detector CT had an overall sensitivity of 82%.

Multiple large, multicenter trials comparing multidetector-row CTC and optical colonoscopy for detecting colorectal polyps and cancers have been published. Earlier multicenter trials had conflicting results. In a study of 1,233 asymptomatic average-risk individuals undergoing colorectal cancer screening, the sensitivities of CTC and colonoscopy for detecting adenomatous polyps ≥ 10 mm were 94% and 88%, respectively. However, in a smaller second study, which included 600 patients referred for clinically indicated colonoscopy, the sensitivities of CTC and colonoscopy for detecting patients with polyps ≥ 10 mm were 55% and 100%, respectively. In a third study, which included 614 individuals at increased risk for colorectal neoplasia, the sensitivities of CTC and colonoscopy were 59% and 98%, respectively. These discrepant results were likely related to differences in study design and reader experience. Older CTC techniques were used in the studies with poor CTC results, and the lack of reader training was likely a major contributing factor. For example, in the third study only 1 of 9 centers involved in that trial had substantial prior experience with CTC, and the only requirement to be a reader was performance of at least 10 CTC procedures (without any test of accuracy). For the institution with prior CTC experience, the sensitivity for polyps ≥ 10 mm was 82%, compared with 24% for the other 8 institutions.

Many of the issues regarding colonic preparation and reader training were addressed in the largest U.S. multicenter trial to date. In the American College of Radiology Imaging Network (ACRIN) National CTC Trial, 15 sites recruited a total of 2,531 asymptomatic patients, who underwent multidetector-row CTC (16 rows or more) with stool and fluid tagging and mechanical carbon dioxide insufflation of the colon. All participating radiologists had to complete a qualifying examination, with a minimum accuracy of 90% for large polyps. Per-patient sensitivity, specificity, and positive and negative predictive values were 90%, 86%, 23%, and 99%, respectively, for detecting ≥ 10 mm adenomas or cancers. The per-patient sensitivity for detecting adenomas ≥ 6 mm was 78%. The per-polyp sensitivity for ≥ 10 mm adenomas or cancers was 84%. When

comparing primary 2-dimensional (2-D) and primary 3-dimensional (3-D) interpretation methods, no difference in sensitivity was identified for the detection of large polyps. A multicenter trial performed in 937 individuals at increased risk for colorectal cancer reported similar per-patient sensitivity, specificity, and negative predictive values of 85%, 88%, and 96%, respectively, for advanced neoplasia ≥ 6 mm, but there was a higher positive predictive value of 62%.

The diagnostic yields of CTC and colonoscopy for advanced neoplasia were compared in parallel screening programs. Primary CTC screening in 3,120 patients was compared with primary colonoscopy screening in 3,163 subjects. Similar detection rates were found for CTC and colonoscopy screening, which identified 123 and 121 advanced neoplasms, respectively. The referral rate for colonoscopy in the CTC group was 8%. The total numbers of polyps removed in the CTC and colonoscopy groups were 561 and 2,434, respectively. Seven perforations occurred in the colonoscopy group, but there were none in the CTC group. A review of a 1-year CTC screening experience for colorectal neoplasia showed that 3.9% of individuals had 1 polyp ≥ 1 cm, and 6.9% had ≥ 1 polyps 6 to 9 mm. Of the 71 patients who chose colonoscopy for further evaluation of these polyps, concordant lesions were found with colonoscopy in 65 (91.5% positive predictive value). In addition, the outcomes of patients with negative CTC screens have also been reported. A longitudinal follow-up of 1,011 patients over nearly 5 years demonstrated a single-interval cancer (crude cancer incidence of 0.2 cancers per 1,000 patient years), leading to the conclusion that a 5-year routine screen interval and nonreporting of diminutive lesions (≤ 5 mm) were appropriate strategies.

CTC performance has been evaluated in senior patient cohorts (age ≥ 65 years). A retrospective analysis of 577 subjects found an excellent CTC-colonoscopy concordance rate of 91%. Based on a 6-mm threshold, there was an overall patient referral rate of 15% for colonoscopy. Considering only adenomas, the per-patient positivity rates for 6- and 10-mm thresholds were 11% and 7%, respectively. When comparing 204 nonsenior (14%) and 250 senior patients (13%) undergoing CTC, another study found no statistically significant difference in the percentage of individuals with at least 1 polyp ≥ 6 mm. A post hoc analysis of 477 senior patients from the ACRIN National CTC Trial demonstrated that for large neoplasms, sensitivity and specificity among the older cohort were 82% and 83%, respectively. There was no statistically significant difference when compared with the sensitivity and specificity of 92% and 86%, respectively, for lesions ≥ 10 mm in the younger patient cohort. For lesions > 6 mm, the sensitivity and specificity were 72% and 86%, respectively, for older patients and 81% and 89%, respectively, for younger patients, with no statistically significant difference. Another study reporting outcomes of 1,400 senior patients who underwent CTC found a 15% frequency for referral to colonoscopy at a polyp threshold of 6 mm. Colorectal neoplasia was identified in 9% of patients, and advanced neoplasia was found in 3%.

Adherence to the ACR practice guideline for performing CTC in adults should help eliminate some of the variability reported in earlier published studies. This guideline also includes suggestions regarding the interpretation and reporting of extracolonic findings. To avoid unnecessary further workup and patient anxiety, caution is emphasized when reporting findings that are likely to be of low clinical significance. There is evidence that using structured reporting constructs, such as CT Colonography Reporting and Data System, can decrease workups to $< 10\%$. Unsuspected extracolonic malignancies and previously unknown aortic aneurysms are detected with CTC examinations in approximately 2% to 3% of patients.

Currently, most third-party payers provide reimbursement for screening CTC only after a failed colonoscopy or, in some cases, for individuals who have a contraindication to colonoscopy (e.g., those on chronic anticoagulation or with severe chronic lung disease who are at risk for undergoing sedation). Several studies have demonstrated the usefulness of CTC in individuals who have undergone an incomplete colonoscopy. In a study of 546 patients who underwent CTC after an incomplete colonoscopy, 13% were found to have lesions ≥ 6 mm. Per-patient and per-lesion positive predictive values of CTC for masses and large polyps were 91% and 92%, respectively.

A meta-analysis comparing the performance of the DCBE with CTC for detecting polyps ≥ 6 mm included 11 studies of DCBE (5,995 patients, 1,548 polyps) and 30 studies of CTC (6,573 patients, 2,348 polyps). Despite the inclusion of CTC studies with older techniques, statistically lower sensitivity and specificity were still seen for the DCBE compared with CTC.

Magnetic Resonance Colonography

MR colonography (MRC), which was introduced approximately 3 years after CTC, has the advantage that it does not use ionizing radiation. However, the spatial resolution of MRC is less than that of CTC, and MRC requires colonic distension with a liquid (a diluted gadolinium solution for "bright lumen" [T1-weighted]) imaging or tap water for "dark lumen" (T1-weighted) imaging. Clinical studies comparing MRC with optical colonoscopy have reported sensitivities of 93% to 100% for polyps ≥ 10 mm. One study compared polyp detection rates between dark and bright lumen MRC in 37 patients. Dark lumen MRC was better, with respective sensitivities of 79% and 68%, respectively, for detecting polyps > 5 mm. Nevertheless, experience with MRC is extremely limited, especially outside of Europe. In a systematic review of 13 prospective studies evaluating MRC performance in 1,285 patients, the per-patient sensitivity and specificity for polyps ≥ 10 mm were 88% and 99%, respectively. On a per-polyp basis, polyps of ≥ 10 mm were detected with a sensitivity of 84%. The data were found to be too heterogeneous for diminutive polyps < 6 mm and for small polyps measuring 6–9 mm.

Role of Local Expertise

Overall, the most appropriate imaging test for colorectal cancer screening is CTC. However, CTC expertise may not be available in all geographic areas. Thus, a DCBE may be the only imaging option in a particular area, despite its lower performance profile. The choice between these 2 tests may ultimately depend on local imaging expertise and on physician and patient preference.

Summary

- CTC has emerged as the leading imaging technique for colorectal cancer screening.
- DCBE remains an imaging test that may be appropriate for colorectal cancer screening, particularly when CTC is not available.
- CTC is the preferred test following an incomplete optical colonoscopy.
- Imaging tests including CTC and barium enema are usually not appropriate for colorectal cancer screening in high-risk patients with hereditary nonpolyposis colorectal cancer and inflammatory bowel disease.

Abbreviations

- CT, computed tomography
- CTC, computed tomography colonography
- DCBE, double-contrast barium enema
- MR, magnetic resonance

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢ ☢	0.1-1 mSv	0.03-0.3 mSv
☢ ☢ ☢	1-10 mSv	0.3-3 mSv
☢ ☢ ☢ ☢	10-30 mSv	3-10 mSv
☢ ☢ ☢ ☢ ☢	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies".		

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Colorectal cancer

Guideline Category

Diagnosis

Screening

Clinical Specialty

Family Practice

Gastroenterology

Internal Medicine

Oncology

Preventive Medicine

Radiology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of initial radiologic examinations for colorectal cancer screening

Target Population

Adult population at average, moderate, and high colorectal cancer risk levels

Interventions and Practices Considered

1. Computed tomography colonography (CTC)
2. X-ray, barium enema
 - Double-contrast
 - Single-contrast
3. Magnetic resonance colonography (MRC)

Major Outcomes Considered

- Mortality
- Utility of radiologic examinations in differential diagnosis and screening

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Staff will search in PubMed only for peer reviewed medical literature for routine searches. Any article or guideline may be used by the author in the narrative but those materials may have been identified outside of the routine literature search process.

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 10 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence (study quality) for each article included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member assigns a rating based on his/her interpretation of the

available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distribute surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The appropriateness rating scale is an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate"; 4, 5, or 6 are in the category "may be appropriate"; and 7, 8, or 9 are in the category "usually appropriate." Each panel member assigns one rating for each procedure for a clinical scenario. The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating.

If consensus is reached, the median rating is assigned as the panel's final recommendation/rating. Consensus is defined as eighty percent (80%) agreement within a rating category. A maximum of three rounds may be conducted to reach consensus. Consensus among the panel members must be achieved to determine the final rating for each procedure.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

This modified Delphi method enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. A more detailed explanation of the complete process can be found in additional methodology documents found on the [ACR Web site](#) (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A cost-effectiveness analysis demonstrated that a double-contrast barium enema (DCBE) performed every 5 to 10 years costs less than \$22,000 per life-year saved for a possible range of natural history, which is far below the standard of \$40,000.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for colorectal cancer screening

Potential Harms

A double-contrast barium enema (DCBE) is a safe procedure, with a perforation rate of approximately 1 in 25,000. The perforation rates associated with other colorectal examinations are 1 in 22,000 for computed tomography colonography (CTC), 1 in 10,000 for a flexible sigmoidoscopy, and 1 in 1,000 for a diagnostic colonoscopy.

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Contraindications

Contraindications

Colonoscopy is contraindicated in patients on chronic anticoagulation or those with severe chronic lung disease who are at risk for undergoing sedation.

Qualifying Statements

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The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical

consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Yee J, Kim DH, Rosen MP, Lalani T, Carucci LR, Cash BD, Feig BW, Fowler KJ, Katz DS, Smith MP, Yaghmai V, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® colorectal cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 12 p. [90 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1998 (revised 2013)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Gastrointestinal Imaging

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Yee J, Rosen MP, Blake MA, Baker ME, Cash BD, Fidler JL, Grant TH, Greene FL, Jones B, Katz DS, Lalani T, Miller FH, Small WC, Sudakoff GS, Warshauer DM, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® colorectal cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2010. 9 p.

Guideline Availability

Electronic copies: Available from the [American College of Radiology \(ACR\) Web site](#) .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the [American College of Radiology \(ACR\) Web site](#) .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria® colorectal cancer screening. Evidence table. Reston (VA): American College of Radiology; 2013. 24 p. Electronic copies: Available from the [ACR Web site](#) .

Patient Resources

None available

NGC Status

This summary was completed by ECRI on March 19, 2001. The information was verified by the guideline developer on March 29, 2001. This NGC summary was updated by ECRI Institute on April 26, 2007. This NGC summary was updated by ECRI Institute on November 30, 2010. This NGC summary was updated by ECRI Institute on February 27, 2014.

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